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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/956,004	09/20/2001	Patrick J. Dillon	PB324D1	1504

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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	3

DATE MAILED: 08/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/956,004	Applicant(s) DILLON ET AL.	
	Examiner Cheyne D Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The art unit designated for this application has changed. Applicants(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Election/Restrictions

The inventions are distinct, each from the other because of the following reasons:

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-8, drawn to an isolated nucleic acid molecule and a method for making a recombinant vector comprising of said nucleic acid molecule, classified in classes 536 and 435, subclasses 23.1 and 440, respectively. If this Group is elected, then the below summarized sequence election is also required.

   II. Claim 9, drawn to a method for producing an E. coli polypeptide, classified in class, 435, subclass 69.1. If this Group is elected, then the below summarized sequence election is also required.

   III. Claims 10-12, drawn to an isolated polypeptide, classified in class 530, subclass 350. If this Group is elected, then the below summarized sequence election is also required.

   IV. Claim 13, drawn to a vaccine, classified in class 424, subclass 184.1. If this Group is elected, then the below summarized sequence election is also required.

   V. Claims 14-16, drawn to an antibody that binds specifically to a polypeptide, classified in class 530, subclass 387.1. If this Group is elected, then the below summarized sequence election is also required.

VI. Claims 17 - 20, drawn a method for detecting a pathogenic E. coli antigen in a sample and a diagnostic kit comprising a container means for containing antibody, a second container means containing a conjugate comprising of said antibody and a label, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is also required.

VII. Claims 21 and 22, drawn to a hybridoma, which produces an antibody specific E. coli pathogenicity island polypeptide, classified in class 435, subclass 346. If this Group is elected, then the below summarized sequence election is also required.

VIII. Claims 23 - 28, drawn to a method for detecting the presence of antibodies specific to the pathogenic E. coli antigen in a sample and a kit for detecting said antibodies comprising of one container means having disposed therein a polypeptide, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is also required.

IX. Claims 29 – 32, drawn to a computer readable medium having recorded thereon a nucleotide sequence, classified in class 211, subclass 41.12. If this Group is elected, then the below summarized sequence election is also required.

X. Claim 33, drawn to computer-based system for identifying fragments of uropathogenic E. coli J96 pathogenicity island PAI IV and PAI V that are homologous to target nucleotide sequences, classified in class 505, subclass 170. If this Group is elected, then the below summarized sequence election is also required.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group draw to amino acid/polypeptide sequence, the Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic sequence (See MPEP § 803.04). It is noted that the multiple of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic sequences effectively impossible to reasonably implement.

MPEP § 803.04 states:

Nucleotides sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction and not a specie election requirement.

In order to facilitate the sequence election of a unique nucleotide sequence from the nucleotide sequences listed in Tables 1-4, it is recommended that the applicant provide the following information for the select nucleotide sequence: contig ID, start (nt) position, stop (nt) position, and match accession number.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and II; III, IV and VIII; V, VI, and VII; IX and X are distinct inventions because they are directed to different chemical types or methods regarding the critical limitations therein. For Groups I and II, the critical feature is a nucleic acid molecule. For Groups III, IV and VIII, the critical feature is a polypeptide. For Groups V, VI, and VII, the critical feature is an antibody. For Groups IX and X, the critical feature is a nucleic acid sequence. Further, it is acknowledged that various processing steps may cause a peptide of Groups III, IV and VIII to be directed as to its synthesis by a polynucleotide of Group I and II, however, the completely separate chemical and entity types of the inventions of the polynucleotide, poplypeptide, antibody, vaccine, and a specific nucleic acid sequence support the undue search burden if they were examined together. Additionally, polynucleotide, poplypeptide, antibodies, and vaccines have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being search separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the four Groupings: [I, II]; [III, IV and VIII]; [V, VI, and VII]; and [IX and X] are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for

using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of E. coli pathogenicity island of Group I, a nucleic acid molecule may be utilized in the distinct usages as in the method of Group II for producing peptides, alternately, for protein functional studies based on *in vitro* or *vivo* expression methods, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

Inventions in Groups III, IV, and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of E. coli pathogenicity island Group III, a polypeptide molecule may be utilized in the distinct usages as in Group IV as a vaccine to elicit protective immune responses to pathogenic E. coli; as in the method of Group VIII, for detecting the presence of antibodies specific to the pathogenic E. coli antigen, alternately, as in a method for determining the degree of affinity between a ligand and its respective receptor in competitive binding assays, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

Inventions in Groups V, VI, and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of E. coli pathogenicity island of Group VII, antibody molecules produced by hybridomas may be utilized in the distinct usages as in Group V, to bind to a specific polypeptide; as in the method of Group VI, for detecting for the presence pathogenic E. coli antigen; alternatively, as in a method for determining the sub-cellular localization of specific antigens via immunocytochemical assays, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

Inventions in Groups IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of E. coli pathogenicity island of Group IX, a computer readable medium having recorded thereon a nucleotide sequences; as in Group X, a computer based system for identifying fragments of uropathogenic E. coli that are homologous to target nucleotide sequences; alternatively, a computer system for manipulating and identifying unique features of said nucleotide sequences, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement e traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

ARDIN H. MARSCHEL
PRIMARY EXAMINER